

product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) that is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes including site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient; or

(3) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

[54 FR 30379, July 20, 1989]

§ 1.720 Conditions for extension of patent term.

The term of a patent may be extended if:

(a) The patent claims a product or a method of using or manufacturing a product as defined in § 1.710;

(b) The term of the patent has never been previously extended except for any interim extension issued pursuant to § 1.760;

(c) An application for extension is submitted in compliance with § 1.740;

(d) The product has been subject to a regulatory review period as defined in 35 U.S.C. 156(g) before its commercial marketing or use;

(e) The product has received permission for commercial marketing or use and—

(1) The permission for the commercial marketing or use of the product is the first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review occurred, or

(2) In the case of a patent other than one directed to subject matter within § 1.710(b)(2) claiming a method of manufacturing the product that primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use is the first received permission for the commercial marketing or use of a product manufactured under the process claimed in the patent, or

(3) In the case of a patent claiming a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and has received per-

mission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and was not extended on the basis of the regulatory review period for use in non-food-producing animals, the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

(f) The application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provisions of law under which the applicable regulatory review period occurred; or in the case of a patent claiming a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or in the case of a patent that claims a new animal drug or a veterinary biological product that is not covered by the claims in any other patent that has been extended, and said drug or product has received permission for the commercial marketing or use in non-food-producing animals, the application for extension is submitted within the sixty-day period beginning on the date of the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal;

(g) The term of the patent has not expired before the submission of an application in compliance with § 1.741; and

(h) No other patent term has been extended for the same regulatory review period for the product.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30380, July 20, 1989]

§ 1.730 Applicant for extension of patent term.

Any application for extension of a patent term must be submitted by the owner of record of the patent or its agent and must comply with the requirements of § 1.740.